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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/583,066

05/30/2000

Erich Wanker

GPCG-P01-122

1672

28120

7590

09/30/2002

ROPES & GRAY
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EXAMINER

MARSCHER, ARDIN H

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 09/30/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/583,066

Applicant(s)

Wanker et al.

Examiner

Ardin Marschel

Art Unit

1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 8, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, and 4-85 is/are pending in the application.
- 4a) Of the above, claim(s) 60-62 and 67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-59, 63-66, and 68-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1, 2, and 4-85 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) attached (sheet) 6) ☐ Other:

Applicants' arguments, filed 7/8/02, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants' election with traverse of Group I, specie A) protein-protein (plus protein-peptide and peptide-peptide interaction), specie B) methods directed to identification of interacting molecules per se, and specie C) readout system also includes a counterselectable genetic element: (then claims 1-59 and 63-66); in Paper No. 15, filed 10/18/01, as modified and responded to in the office action, mailed 12/31/01, is acknowledged. Applicants have reiterated the traversal argument that claims 60-62 and 67 do not pose a serious burden of examination. It is noted that this argument fails to acknowledge that the burden is based on an undue search burden and not an undue examination burden per se. Consideration of amended claims 60-62 and 67 reveals that they are still directed to production methods which are deemed now a non-elected specie within Group I.

This requirement is still deemed proper and is therefore made FINAL.

Claims 1, 2, 4-59, 63-66, and 68-85 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while

being enabling for the providing of host cells containing at least one genetic element, or protein or peptide cloned therefrom, which itself lacks an activation domain for the readout system while yet activating said readout via interaction with another appropriate genetic element, does not reasonably provide enablement for any "generic" genetic element, or protein or peptide cloned therefrom, which is capable of activating the readout system via interaction with another appropriate genetic element. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in

molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

This rejection is reiterated and maintained from the previous office action, mailed 12/31/01, and as necessitated by amendment regarding newly submitted claims. Applicants firstly review the false positive conditions and characterize the class 4 false positive as actually not being a false positive. This is acknowledged. Applicants then set forth the argument that preselection steps (B) prevent the false positives of classes 1-3. In response the host cell preselection step (B) is acknowledged as preventing false positives by genetic elements with a marker in host cells prepared in step (A). It is pointed out, however, that step (C) combines at least two genetic elements in host cells neither of which are required to be screened in the host cells in step (B). This lack of screening the genetic elements in step (C) by referring to a type (B) step leaves the host cells with unscreened genetic elements which arbitrarily may activate the read-out system without any interactions as desired in lines 1-2 of claim 1, for example. This lack of enablement still exists in the instant claims and still is deemed a proper basis for this scope of enablement rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 65 and 66 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Vidal et al. [PNAS 93:10315(1996)].

This rejection is reiterated and maintained from the previous office action, mailed 12/31/01. Applicants have not argued the rejection of instant claim 65 and 66 which are still deemed to be anticipated by Vidal et al. as they do not require any preselection steps but only visual differentiation in different activation states of the readout system. Vidal et al. clearly does provide such visual differentiation via cell growth or not as previously set forth in the previous office action, mailed 12/31/01.

Claim 65 is rejected under 35 U.S.C. § 102(b) and (e) as being clearly anticipated by Fields et al. (P/N 5,283,173).

This rejection is reiterated and maintained from the previous office action, mailed 12/31/01. Applicants argue that visual means for differentiating different activation states are not disclosed in Fields et al. In response as set forth in the previous office action, mailed 12/31/01, Fields et al. discloses the usage of host cells which are visually differentiated by the GAL4 protein which permits growth on galactose as noted in column 6, lines 53-68, which taken with the remainder of the patent which is directed to the detection of protein-protein interaction via genetic element interaction as required in the kit part (Q) of claim 65 anticipates the above instant claim.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35

U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 65 and 66 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fields et al. (P/N 5,283,173).

This rejection is reiterated and maintained from the previous office action, mailed 12/31/01. Applicants argue that Fields et al. does not suggest a kit with host cells which allows host selection via a counter-selected marker readout system. In response only claims 65 and 66 remain rejected hereinunder which also do not require such a counter-selection marker. Applicants further argue that Fields et al. also lacks a visual means of readout. This has been responded to above as non-persuasive in that the growth or not of host cells is a visual marker readout system which supports the maintaining of this rejection.

No claim is allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

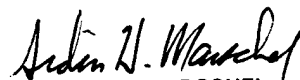
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 26, 2002


ARDIN H. MARSCHEL
PRIMARY EXAMINER